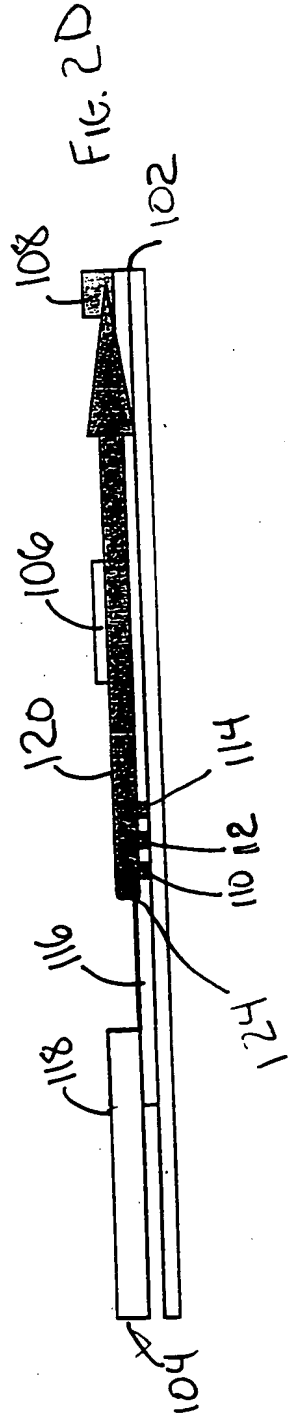
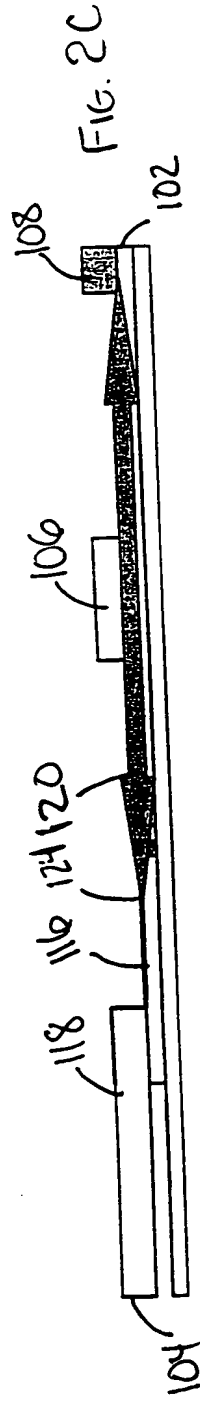
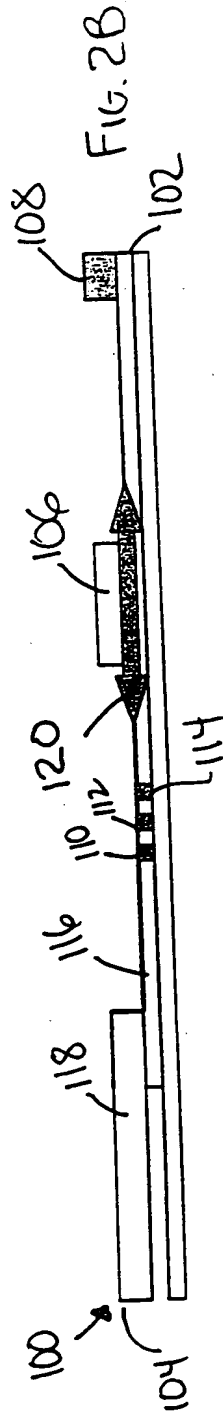
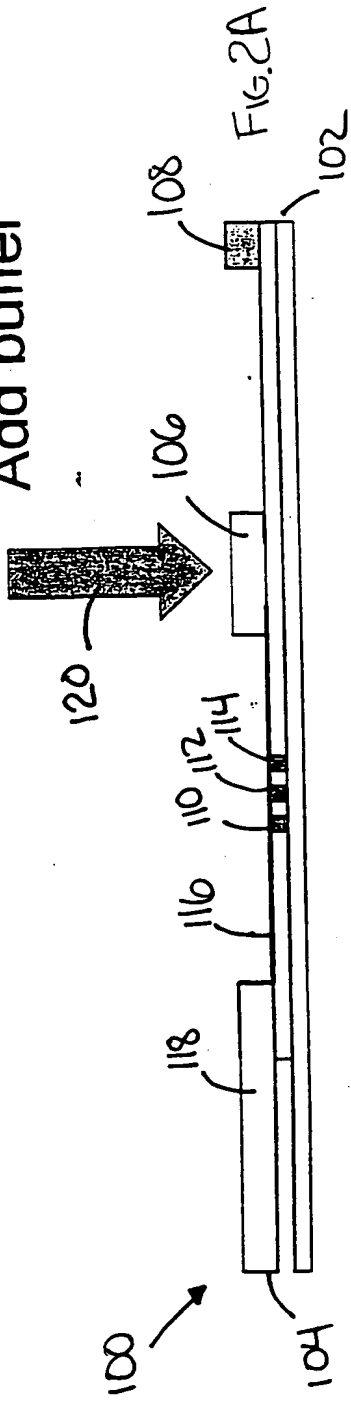


Add buffer



Add sample

Add buffer

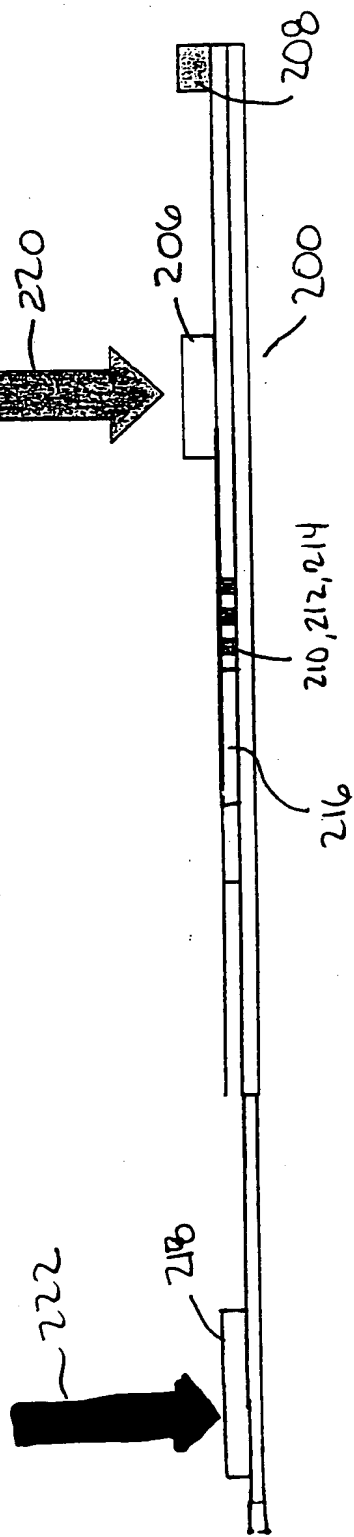


FIG. 3A

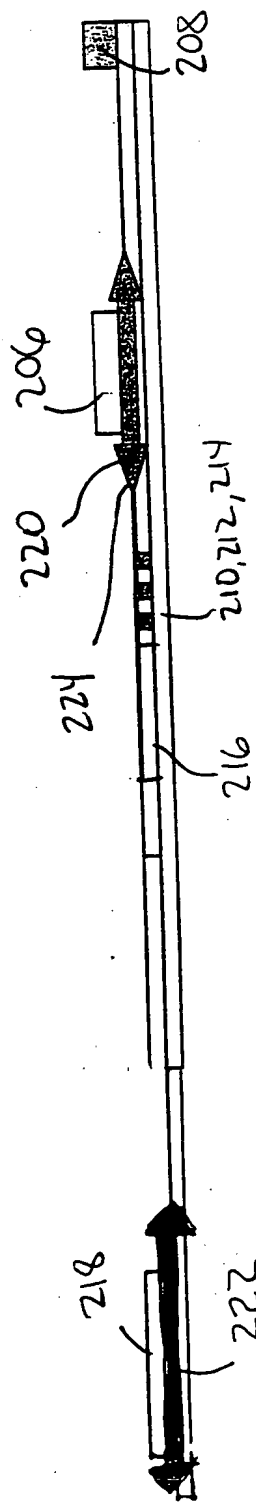


FIG. 3B

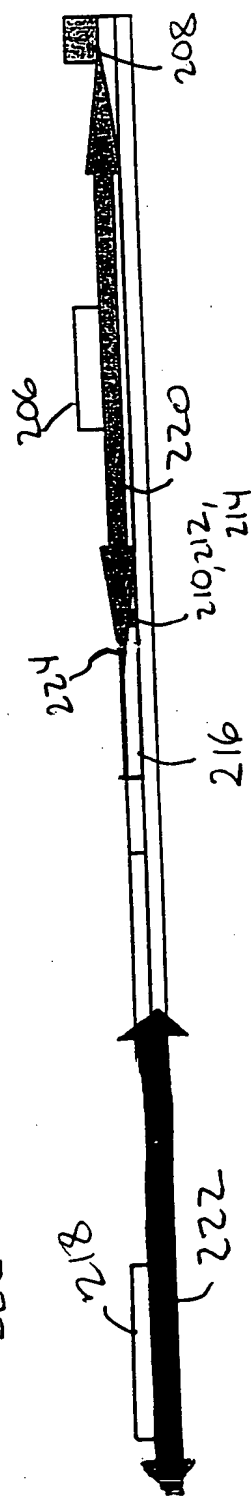


FIG. 3C

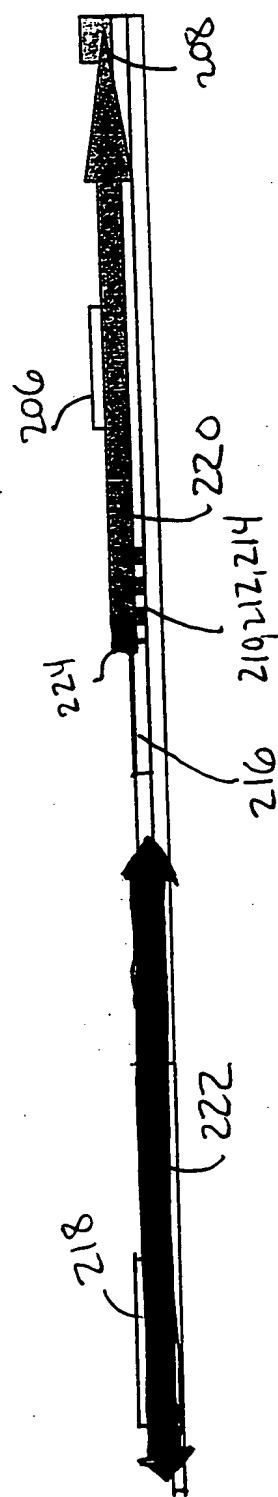


FIG. 3D

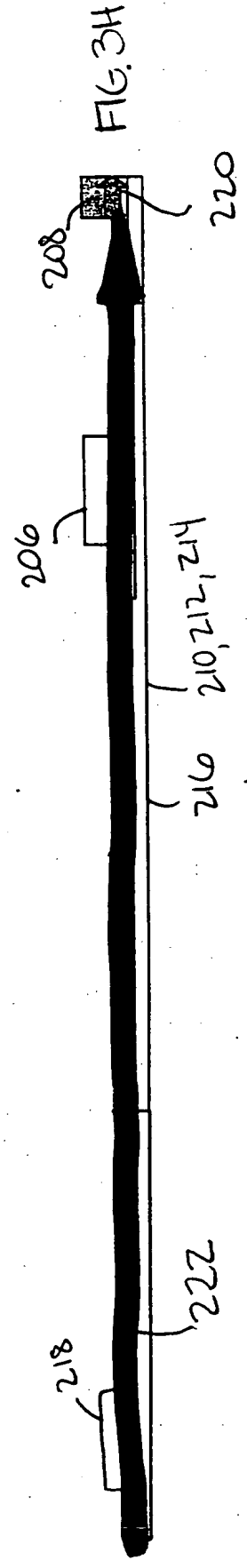
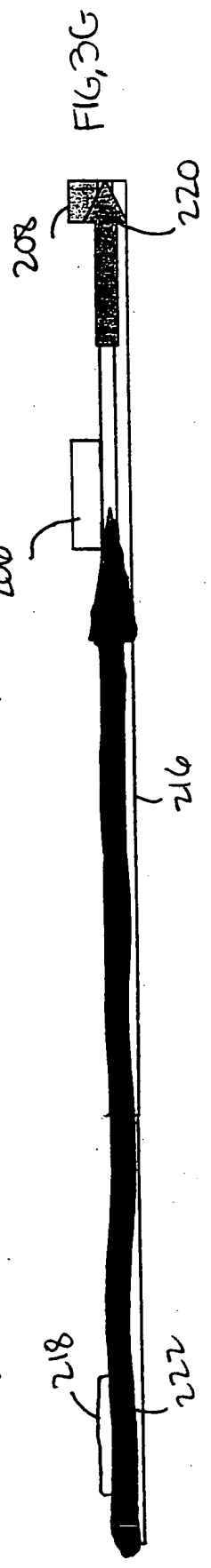
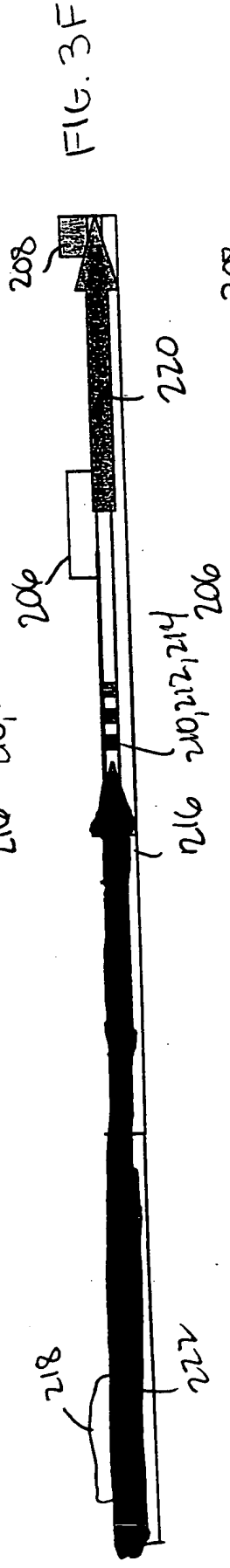
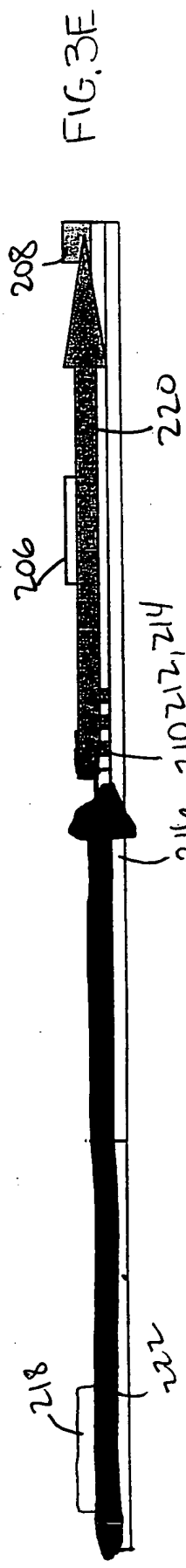


FIG. 4

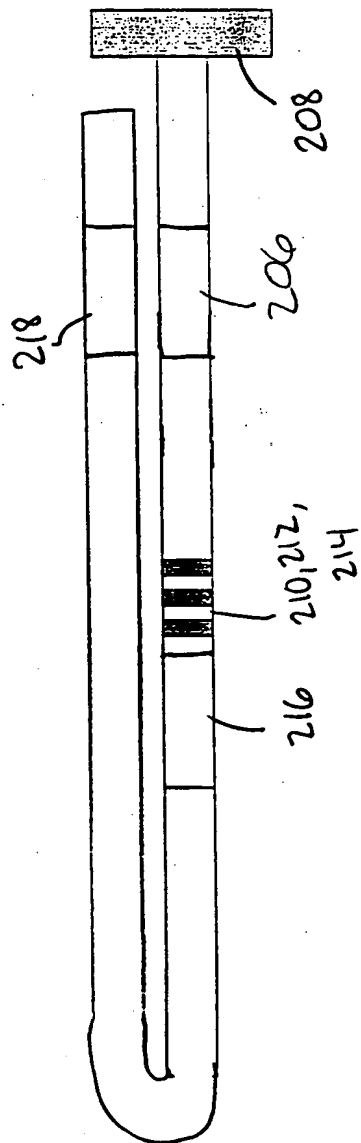


FIG. 5A

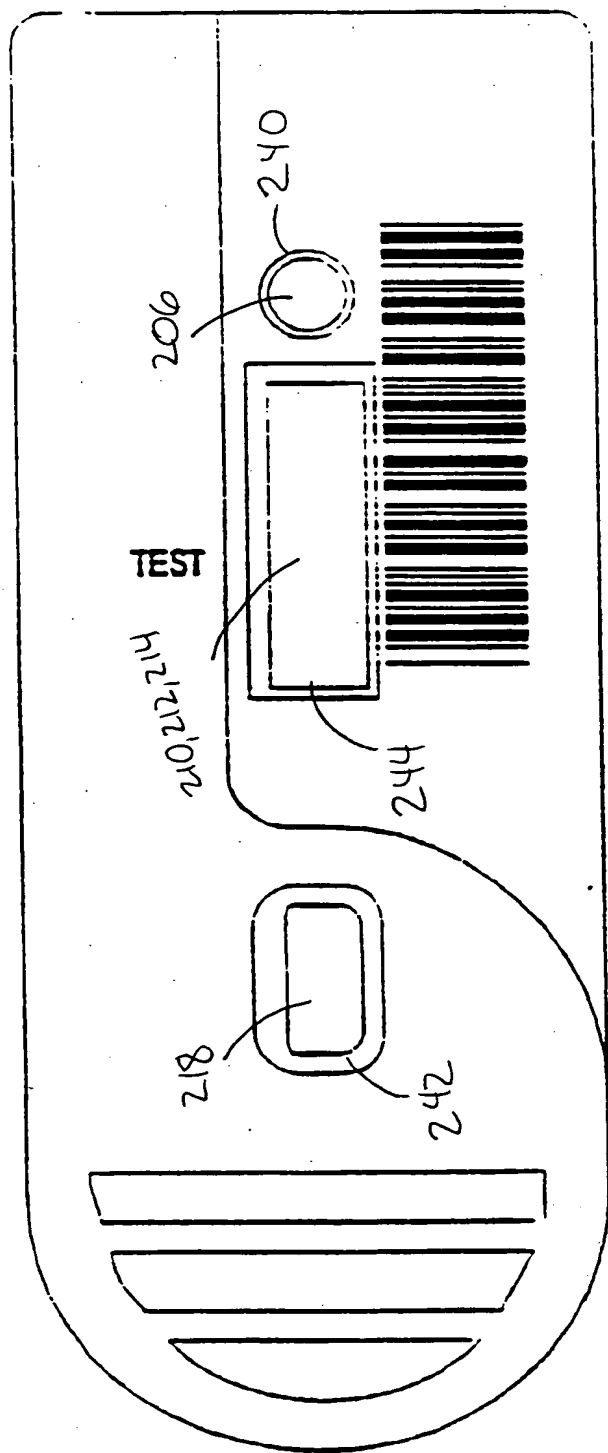


FIG. 5B

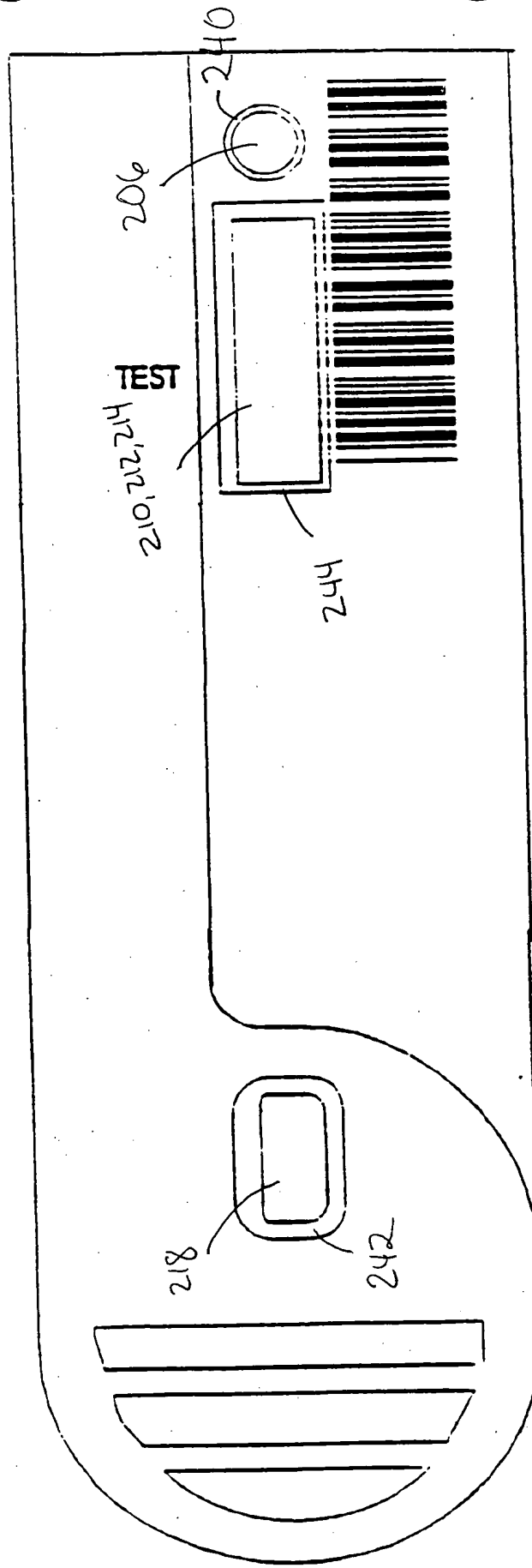


FIG. 5C

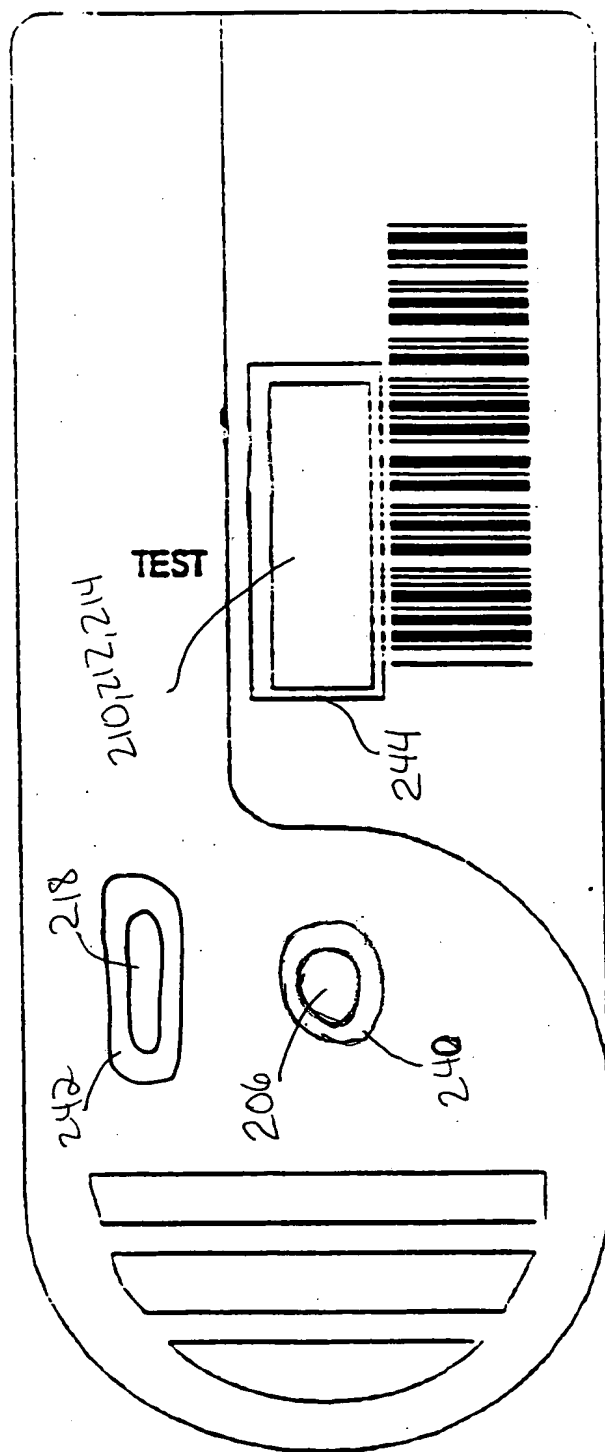


FIG. 6A

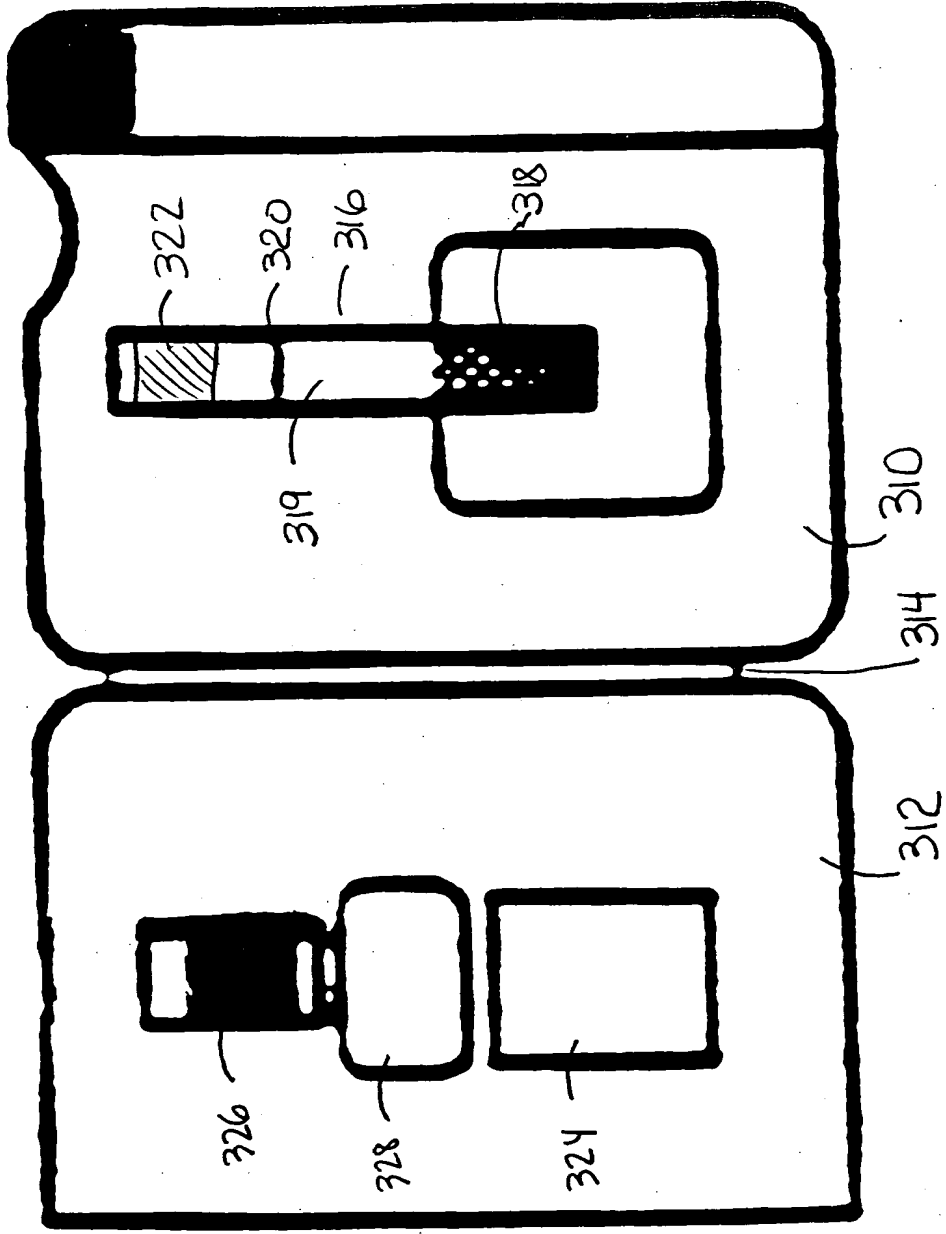
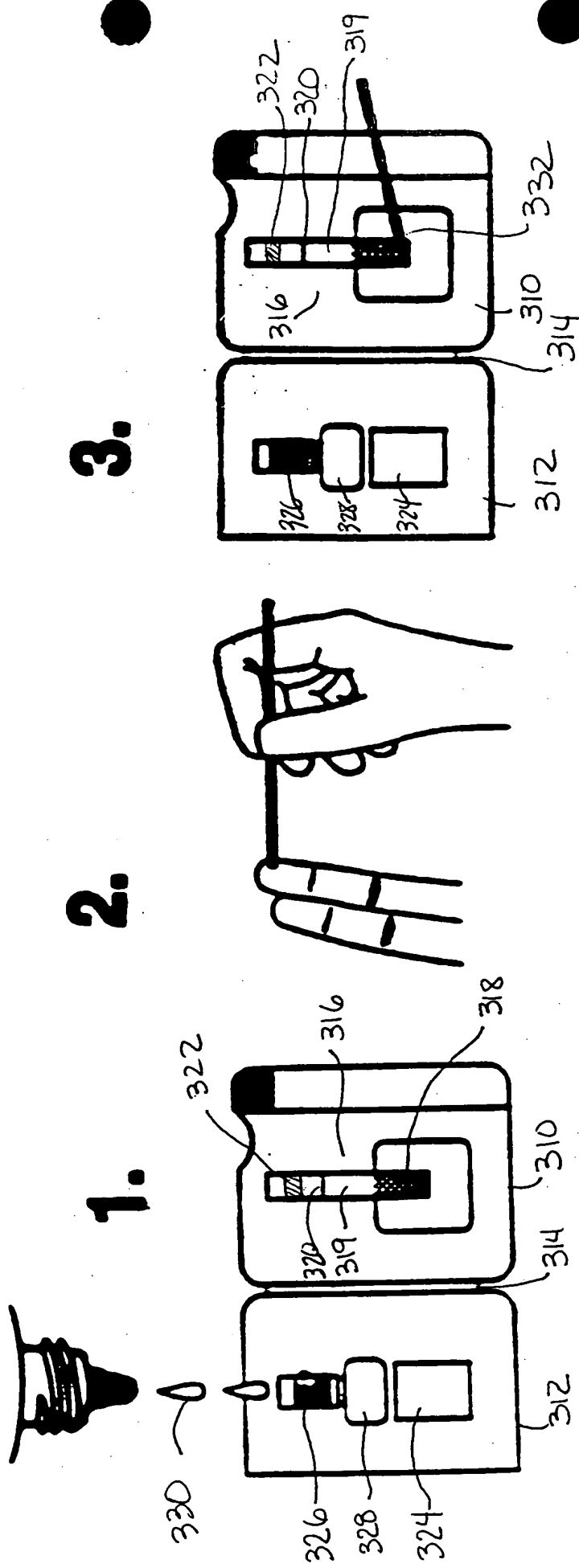


FIG. 6B



ReLIA™ TSH (Goat Capture) 160 µg/ml BSA-DNP in Release Buffer

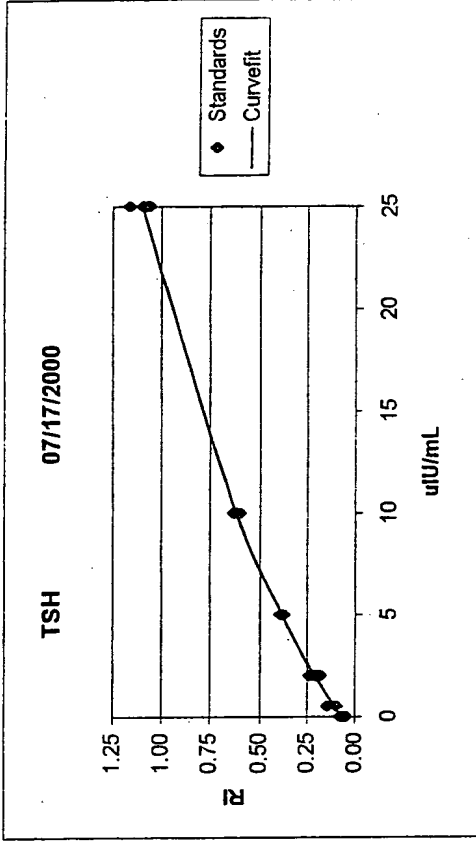
FIGURE 8

Sample	Sheet	Instrument	Hc (Dr)	Lc (Dr)	Specimen (Dr)	Hc/Lc	Specimen/HC	uIU/ml
4A	56R	104	0.3229	0.2308	0.2153	1.399	0.6667	9.21
4A	53R	120	0.3306	0.2371	0.2073	1.394	0.6270	8.48
4A	41R	110	0.3002	0.2394	0.2010	1.254	0.6695	9.26
4A	37R	163	0.3252	0.2569	0.2112	1.266	0.6496	8.89
4A	33R	115	0.2941	0.2414	0.1942	1.218	0.6605	9.08
4A	29R	107	0.3031	0.2080	0.1980	1.457	0.6532	8.95
4A	27R	146	0.3375	0.2200	0.1980	1.534	0.5867	7.74
4A	24R	111	0.3136	0.2235	0.2010	1.403	0.6410	8.72
4A	21R	104	0.2995	0.2119	0.2024	1.413	0.6755	9.37
4A	18R	120	0.3213	0.2291	0.1959	1.403	0.6097	8.16
4A	14R	110	0.2902	0.2105	0.1917	1.378	0.6607	9.10
4A	12R	163	0.3176	0.2333	0.2128	1.361	0.6699	9.27
4A	9R	115	0.3156	0.2243	0.2050	1.407	0.6494	8.88
4A	7R	107	0.3170	0.2213	0.2140	1.432	0.6751	9.37
4A	4R	146	0.3367	0.2329	0.2110	1.446	0.6265	8.46
4A	3R	111	0.3409	0.2426	0.2237	1.405	0.6562	9.01
AVG			0.3166	0.2289	0.2052	1.3856	0.6486	8.87
STD DEV			0.0158	0.0132	0.0089	0.0799	0.0250	0.46
%CV			5.0	5.7	4.3	5.8	3.9	5.2

TSH (RI = antigen Dr/HC Dr)

FIGURE 9

Standard	RI	Standards	Fitted RI
0.0	0.046	0	0.060
0.0	0.049	0.5	0.104
0.0	0.058	2.0	0.210
0.0	0.078	5.0	0.384
0.5	0.094	10.0	0.618
0.5	0.0945	25.0	1.098
0.5	0.0995		
0.5	0.1471		
2.0	0.1801		
2.0	0.2365		
2.0	0.2146		
2.0	0.1970		
5.0	0.3889		
5.0	0.3788		
5.0	0.3926		
5.0	0.3730		
10.0	0.6198		
10.0	0.6262		
10.0	0.6301		
10.0	0.6026		
25.0	1.0938		
25.0	1.0580		
25.0	1.0755		
25.0	1.1618		



chi-squared

0.57

K0

49.7910

K1

0.9165

K2

2.9872

K3

0.0604

Standards:	0 uIU/ml	0.5 uIU/ml	2 uIU/ml	5 uIU/ml	10 uIU/ml	25 uIU/ml
	0.046	0.094	0.1801	0.3889	0.6198	1.0938
	0.049	0.0945	0.2365	0.3788	0.6262	1.0580
	0.058	0.0995	0.2146	0.3926	0.6301	1.0755
	0.078	0.1471	0.1970	0.3730	0.6026	1.1618

Mean:

0.058

0.109

0.383

1.097

SD:

0.014

0.026

0.009

0.045

CV

24.62

23.67

11.67

1.96

Standards:	0 uIU/ml	0.5 uIU/ml	2 uIU/ml	5 uIU/ml	10 uIU/ml	25 uIU/ml
	0.00	0.37	1.56	5.08	10.036	24.850
	0.00	0.38	2.42	4.894	10.191	23.443
	0.00	0.45	2.08	5.155	10.286	24.124
	0.18	1.08	1.81	4.786	9.626	27.690

Mean:

0.046

0.570

1.967

25.027

SD:

0.092

0.342

0.372

0.291

CV

200.00

59.91

18.90

3.42

2.90

7.46

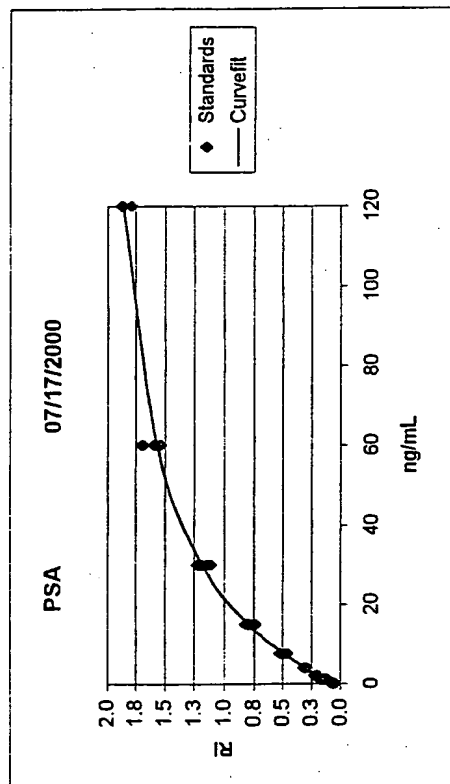
ReLIA™ PSA (Goat Capture) 160 µg/ml BSA-DNP in Release Buffer

FIGURE 10

Sample	Sheet	Instrument	Hc (Dr)	Lc (Dr)	Specimen (Dr)	Hc/Lc	Specimen/HC	ng/ml
2A	HF 135-24	163	0.2438	0.2469	0.1206	0.987	0.4948	9.70
2A	HF 135-23	165	0.2243	0.2252	0.0969	0.996	0.4318	8.20
2A	HF 135-20	104	0.2883	0.2543	0.1352	1.134	0.4690	9.07
2A	HF 135-21	120	0.2188	0.2165	0.0996	1.011	0.4553	8.75
2A	HF 135-31	115	0.2448	0.2113	0.1123	1.159	0.4586	8.83
2A	HF 135-30	107	0.2301	0.2283	0.1177	1.008	0.5117	10.11
2A	HF 135-27	111	0.2149	0.1825	0.1094	1.177	0.5089	10.05
2A	HF 135-25	146	0.2329	0.2206	0.1078	1.056	0.4629	8.93
2A	HF 135-36	163	0.2907	0.2558	0.1342	1.136	0.4617	8.90
2A	HF 135-35	165	0.3104	0.2988	0.1237	1.039	0.3984	7.45
2A	HF 135-33	104	0.2467	0.2507	0.1133	0.984	0.4595	8.85
2A	HF 135-34	120	0.2424	0.2270	0.1288	1.068	0.5313	10.62
2A	HF 135-18	115	0.2535	0.2529	0.1150	1.002	0.4535	8.71
2A	HF 135-37	107	0.2784	0.2633	0.1300	1.057	0.4672	9.02
2A	HF 135-19	111	0.2702	0.2701	0.1158	1.000	0.4288	8.14
2A	HF 135-29	146	0.2624	0.2314	0.1185	1.134	0.4515	8.66
AVG			0.2533	0.2397	0.1174	1.0593	0.4653	9.00
STD DEV			0.0279	0.0275	0.0112	0.0673	0.0334	0.80
%CV			11.0	11.5	9.5	6.4	7.2	8.9

PSA
0706-HF135

Figure 11



0.0	0.0713	0.0	0.076
0.0	0.0606	1.0	0.130
0.0	0.0641	2.0	0.187
0.0	0.0511	4.0	0.301
1.0	0.1178	7.5	0.481
1.0	0.1126	15.0	0.789
1.0	0.1754	30.0	1.182
1.0	0.1501	60.0	1.565
1.0	0.1202	120.0	1.853

0.0	0.0713	0.0	0.0606	0.0	0.0641	0.0	0.0511	1.0	0.1178	1.0	0.1126	1.0	0.1754	1.0	0.1501	1.0	0.1202	1.0	0.1432	2.0	0.1927	2.0	0.1832	2.0	0.1933	2.0	0.2127	4.0	0.3082	4.0	0.2926	4.0	0.3007	4.0	0.2891	7.5	0.4709	7.5	0.5187	7.5	0.4582	7.5	0.5072	15.0	0.8110	15.0	0.7819	15.0	0.7861	15.0	0.7382	30.0	1.2190	30.0	1.1140	30.0	1.1931	30.0	1.1507	60	1.5443	60.0	1.5863	60.0	1.5426	60.0	1.6945	120.0	1.7872	120.0	1.8674
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Chi-squared

1.53

K0	28.1760
K1	1.0984
K2	2.1378
K3	0.0764

	0 ng/ml	1 ng/ml	2 ng/ml	4 ng/ml	7.5 ng/ml	15 ng/ml	30 ng/ml	60 ng/ml	120 ng/ml
0.000	0.0713	0.1178	0.1927	0.3082	0.4709	0.8110	1.2190	1.5443	1.7872
0.001	0.0606	0.1126	0.1932	0.2926	0.5187	0.7919	1.1140	1.5863	1.8674
0.002	0.0641	0.1754	0.1933	0.3007	0.4582	0.7861	1.1931	1.5426	
0.005	0.0511	0.1501	0.2127	0.2891	0.5072	0.7382	1.1507	1.6945	

12

Mean
SD
CV

0 ng/ml	1 ng/ml	2 ng/ml	4 ng/ml	7.5 ng/ml	15 ng/ml	30 ng/ml	60 ng/ml	120 ng/ml
0.00	0.79	2.09	4.14	7.29	15.63	31.95	57.56	99.70
0.00	0.70	1.93	3.86	8.29	14.79	26.72	62.64	125.63
0.00	1.79	2.10	4.00	7.02	14.91	30.57	57.36	
0.00	1.36	2.44	3.79	8.05	13.58	28.44	79.25	

ng/ml

0.83
1.24

Mean
SD
CV

	0.00	1.12	2.04	3.95	7.53	14.73	29.42	60.10	112.66
Mean	0.00	1.12	2.04	3.95	7.53	14.73	29.42	60.10	112.66
SD	0.00	0.42	0.10	0.15	0.67	0.85	2.31	3.59	18.33
CV		37.74	4.80	3.92	8.88	5.79	7.86	5.98	16.27

FIGURE 12

Comparison of ReLIA TSH Assay With Sample Added to Top and Bottom Ports Versus Sample Added to Bottom Port Only

		Sample Added to Top				No Sample Added to Top			
Sample		HCDR	Specimen DR	<u>Specimen DR</u>	TSH (uIU/mL)	HCDR	Specimen DR	<u>Specimen DR</u>	TSH (uIU/mL)
				HCDR				HCDR	
S-25 Spiked	Mean	0.2499	0.0243	0.0973	1.9088	0.204	0.0249	0.1262	2.4425
	SD	0.0154	0.017	0.0054	0.101	0.0359	0.007	0.0292	0.5276
	CV	6.2%	7.0%	5.5%	5.3%	17.6%	2.9%	23.1%	21.6%
S-42 Spiked	Mean	0.2566	0.0869	0.3399	6.2871	0.2219	0.0895	0.4066	7.4928
	SD	0.0199	0.0054	0.0275	0.4981	0.0249	0.0057	0.0281	0.5252
	CV	7.8%	6.3%	8.1%	7.9%	11.2%	6.4%	6.9%	7.0%
Pool A	Mean	0.2541	0.1369	0.5436	10.1692	0.2338	0.1394	0.6035	11.418
	SD	0.0312	0.0093	0.0497	1.0085	0.0362	0.0133	0.0575	1.4461
	CV	12.3%	6.8%	9.2%	9.9%	15.5%	9.6%	11.2%	12.7%
Pool B	Mean	0.2613	0.031	0.1186	2.308	0.2147	0.0289	0.1358	2.6254
	SD	0.0164	0.0021	0.0082	0.1526	0.0289	0.0025	0.0128	0.2336
	CV	6.3%	6.8%	6.9%	6.6%	13.4%	8.7%	9.4%	8.9%

FIGURE 13

Reproducibility of the ReLIA TSH Assay With Sample added to Top and Bottom

TSH LEVEL

ReLIA Result in uIU/mL (N = 8 Replicates)

Normal (Approx. 1 uIU/mL)	Mean	1.0712
	SD	0.089
	CV	8.3%
Borderline Elevated (Approx. 5 uIU/mL)	Mean	6.2425
	SD	0.551
	CV	8.8%
Elevated (Approx. 25 uIU/mL)	Mean	23.631
	SD	1.658
	CV	7.0%

FIGURE 14

